REMARKS

This responds to the Office Action mailed on June 24, 2009.

Claims 57, 62, 68, and 78 are amended, and claims 79-81 are added; as a result, claims 57-64, 68, 71-76, and 78-81 are now pending.

The Examiner is thanked for the courtesy of the telephonic interview on September 3, 2009, in which the enablement rejection was discussed.

The 35 U.S.C. § 112 Rejection

Claims 57-64, 67-68, 71-76, and 78 were rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate enablement. This rejection, as it may be maintained with respect to the pending claims, is respectfully traversed.

The Examiner asserts that Applicant's specification does not disclose concentrations of cysteine or any sulfhydryl containing agent that would produce the desired result, given the teachings of unpredictability disclosed in the Jones Declaration. In particular, the Examiner asserts that 100 mg/L cysteine did not enhance the transformation of *Brachypodium distachyon*, that concentrations there were lower or higher than 300 to 350 mg/L cysteine did not significantly effect or resulted in inhibition of the transformation of corn, and that combinations of cysteine with other sulfhydryl containing agents, such as ascorbic acid or glutathione, or other media constituents, e.g., silver nitrate, had unpredictable effects.

It is Applicant's specification that discloses that sulfhydryl containing agents as a class and in certain concentrations may enhance the stable transformation of a wide variety of plant cells or tissue. For example, the Examiner is requested to consider that all of the sulfhydryl-containing agents tested, i.e., DTT, glutathione, cysteine and sodium thiosulfate, were effective at enhancing *Agrobacterium*-mediated transformation of soybean (see Table 2 in the specification). Also, Tables 3-4 in the Jones Declaration (filed on April 6, 2009) provide evidence that co-culturing corn on glutathione containing solid media enhances *Agrobacterium*-mediated transformation of corn. Moreover, the Examiner is also requested to consider Olhoft et al. (Planta, 216:723 (2003)) (copy enclosed) reported that mixtures of L-cysteine, DTT and sodium thiosulfate in solid co-cultivation media enhanced stable transformation of soybean relative to explants treated with only one of the agents (see Tables 2-4).

Applicant has provided more than sufficient evidence, e.g., including post-filing data evidence including journal articles and data described in the Jones Declaration, that numerous sulfhydryl containing agents in solid co-cultivation media at more than one concentration and in different types of plant cells or tissue enhances *Agrobacterium*-mediated transformation. It is well-settled that it is not necessary that applicant have prepared and tested all the embodiments of the invention in order to meet the requirements of § 112. In re Angstadt, 190 U.S.P.Q. 214, 218 (C.C.P.A. 1976). Therefore, the requisite predictability that sulfhydryl containing agents including cysteine at concentrations of at least 100 mg/L in solid co-cultivation media enhance *Agrobacterium*-mediated transformation in plant cells or tissue, has been shown.

And although all sulfhydryl containing agents at every concentration, or in combination with other reagents, may not enhance stable transformation of every plant cell or tissue, the Examiner is reminded that the claims are directed to a method for stable transformation of monocot plant tissues or cells with cysteine which is present in an amount effective to enhance *Agrobacterium*-mediated transformation. As such, any inoperative embodiment is not included within the scope of the claims. In re Angstadt, 537 F.2d 498, 190 U.S.P.Q. 214 (C.C.P.A).

The Examiner further asserts that the state of the art teaches that specific conditions and chemical components are required to achieve a successful transformation of a plant, and that in the absence of guidance, it would require undue trial and error for one of ordinary skill in the art to test the and evaluate the multitude of cysteine concentrations either alone or in combination with other agents and to test different plants to find those that increase transformation efficiencies.

As discussed in the Amendment filed on April 6, 2009, it is Applicant's position that media and target explants to transform a wide variety of plants were known to the art prior to Applicant's filing. See, e.g., Enriquez-Obregon et al. (Biotechnologia Aplicada, 14:169 (1997)) (transformed sugarcane) and Perl et al. (Biotechnology, 14:624 (1996)) (transgenic grape), references previously cited against the claims under 35 U.S.C. § 102 and/or § 103, as well as Bidney et al. (Plant Molecular Biology, 18:301 (1992)) (transgenic tobacco and sunflowers), Liu et al. (Plant J., 23:687 (2000)) (transgenic wheat), Ku et al. (Nat. Biotech., 17:76 (1999)) (transgenic rice), the abstract for Gould et al. (Plant Physiol., 95:426 (1991)) (transgenic maize), and the abstracts for Lynch et al. (J. Econ. Entomol., 92:246 (1999)) (transgenic corn), Schenk

et al. (Plant Mol. Biol., 39:1221 (1999)) (transgenic banana), Srivastava et al. (Proc. Natl. Acad. Sci. USA, 96:11117 (1999)) (transgenic wheat), and Kohli et al. (Plant J., 17:591 (1999)) (transgenic rice) (a copy of those abstracts was enclosed with the Amendment filed on September 17, 2008 or the Amendment field on April 6, 2009, and those abstracts are cited on Forms 1449 which accompany this Amendment). Applicant need not teach what is well-known to the art. Hybritech Inc. v. Monoclonal Antibodies, Inc., 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986).

Further, the fact that the outcome of a screening program to identify sulfhydryl containing agents useful alone, e.g., at certain concentrations, or in combination with other reagents to enhance *Agrobacterium*-mediated transformation in plant cells or tissue, may be unpredictable is precisely why a program is carried out. The Examiner simply cannot reasonably contend that a program to locate biomolecules with target biological or physical properties would not be carried out by the art because the results cannot be predicted in advance.

In fact, the Federal Circuit has explicitly recognized that the need, and methodologies required, to carry out extensive synthesis and screening programs to locate biomolecules with particular properties do not constitute undue experimentation. In re Wands, 8 U.S.P.Q.2d 1400, 1406-1407 (Fed. Cir. 1988), the Court stated:

> The nature of monoclonal antibody technology is that it involves screening hybridomas to determine which ones secrete antibody with desired characteristics. Practitioners of this art are prepared to screen negative hybridomas in order to find one that makes the desired antibody.

Likewise, practitioners in the art related to the present application would be well-equipped to screen sulfhydryl containing agents to identify agents useful to enhance *Agrobacterium*-mediated transformation of plant tissue or cells. See also, Hybritech Inc. v. Monoclonal Antibodies Inc., 231 U.S.P.Q. 81, 84 (Fed. Cir. 1986) (evidence that screening methods used to identify characteristics [of monoclonal antibodies] were available to art convincing of enablement). Accordingly, the fact that a given claim may encompass a variety of agents at a range of concentrations and numerous types of plants, is not dispositive of the enablement issue, particularly in an art area in which the level of skill is very high and in which screening of large numbers of compounds has been standard practice for at least ten years (Ex parte Forman, 230 U.S.P.Q.2d 456 (Bd. App. 1986).

Therefore, withdrawal of the § 112, first paragraph, enablement rejection is respectfully requested.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's representative at (612) 373-6959 to facilitate prosecution of this application.

If necessary, please charge any additional fees or deficiencies, or credit any overpayments to Deposit Account No. 19-0743.

Respectfully submitted,

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Date September 22, 2009

By / Janet Embretson /
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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 22nd day of September, 2009.

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Signature